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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,486	07/31/2003	Daniel Afar	67789-354	6413
50670 7590 05/16/2007 DAVIS WRIGHT TREMAINE LLP 865 FIGUEROA STREET SUITE 2400 LOS ANGELES, CA 90017-2566			EXAMINER WAGHRAY, ANURADHA	
			ART UNIT 1609	PAPER NUMBER
			MAIL DATE 05/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/633,486

Applicant(s)

AFAR ET AL.

Examiner

Anu Waghray

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/10/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment</u> . |

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DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group III in the reply filed on 01/19/07 is acknowledged. The traversal is on the ground(s) that the claimed inventions in groups I-V are all involved with cancer and are therefore coextensive. Although all the claims are drawn to cancer but the claims are drawn to nucleic acid, polypeptide and antibodies that are patentably distinct products with different structures and functions. Therefore the search is not coextensive. Further the applicant claims a long list of genes (Table 1A-C) to be examined that have distinct and unrelated sequences. Because the sequences do not overlap in scope and are not obvious variants they have materially different design, therefore there is serious sequence search and literature search burden. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-13 and 21-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 19,2007.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective

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because: the date of the provisional application is entered wrong. Instead of entering july 31st 2002 the applicant entered July 31st 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 14 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 drawn to an antibody that binds to a polypeptide having a nucleic acid sequence as shown in tables 1A-C. The claim is vague and indefinite because the polypeptides do not comprise of nucleic acid sequences. Further, the tables 1 A-C show unigene cluster identification numbers for the list of genes and do not show nucleotide sequences. Therefore, it is suggested that the applicant amend the claim to recite "polypeptide encoded by Seq ID No:1"

Claims 16-18 are drawn to conjugating the antibody with an effector component. It is not clear what the effector component is effecting. Is the component effecting the antibody or is the antibody effecting the component?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Weidle.et.al. (WO/98/10065, published on 5/12/98). Please note that US2002/0127579 document is an English language equivalent of WO/98/10065. While the publication date of WO/98/10065 is relied upon for the rejection of claims 14-16, passages from the English language (US2002/0127579) document are cited in the interest of compact prosecution.

Claims 14-16 are drawn to an antibody against epithelial membrane protein-1 that binds to a polypeptide having a sequence shown in Seq ID # 1, the antibody is further conjugated to an effector component.

Weidle.et.al. anticipates a polypeptide comprising of the instantly claimed Seq ID # 1, see the attached sequence alignment of Seq ID #1 with the sequence disclosed by Weidle.et.al. Weidle.et.al. also anticipates antibody specific to the instant Seq ID No:1 (example 7, page 6 of US2002/0127579). It is also well known in the antibody art that an antibody generated against a specific polypeptide sequence will cross react with any other protein that has identical or similar sequence. Therefore, the antibody anticipated by Weidle.et.al. will cross-react with EMP-1 polypeptide.

Claim 16 is drawn to an antibody conjugated to an effector component. Weidle.et.al. teaches an antibody conjugated to a toxin or an enzyme (page 2, paragraph 0039 of US2002/0127579). Therefore the reference teaches such a composition.

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As the reference teaches a polypeptide sequence identical to EMP-1 sequence and an antibody generated from the same sequence and it also teaches antibody conjugated to an effector molecule the reference anticipates claims 14-16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weidle et al. (WO/98/10065, published on 5/12/98), and Taylor et al. (WO/1997/19171)

Claims 17-20 are drawn to a humanized antibody or antibody fragment conjugated to an effector component wherein the effector component is a fluorescent-labeled radioisotope or a cytotoxic chemical.

As stated above, Weidle et al. teaches an antibody and in addition, Weidle et al. teaches an antibody conjugated to a toxin (page 7, paragraph 25). However, Weidle et al. do not teach humanized antibody or antibody fragment conjugated to a fluorescent label or a radioisotope. Taylor et al., teaches a humanized antibody or an antibody fragment (page 18, line 15) and antibodies conjugated to fluorescent label (Figure 10, page 9). Taylor et al., labeled the secondary antibody to identify localization of EMP-1.

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The combined teachings of Weidle.et.al and Taylor.et.al would motivate one skilled in the art at the time of invention was made to make a humanized antibody because it is well known in the art that humanized antibody reduces immunogenicity and it may be preferable for *in vivo* use.

Further, although Taylor.et.al did not teach fluorescent labeling of the primary antibody, it would be much cheaper and more practical to conjugate the primary antibody with the fluorescent label. Therefore, one would be motivated to fluorescent label the antibody of Weidle.et.al in a similar manner as taught by Taylor.et.al for easy detection of the protein level.

The labeling of an antibody either with a radioisotope or a cytotoxic chemical are two alternative methods for use in treatment. Weidle.et.al teaches an antibody conjugated to a toxin (page 7, paragraph 25). Therefore, antibody conjugated with a cytotoxic chemical would serve the same purpose as that conjugated with a radioisotope.

Therefore, there would have been reasonable expectation of success in modifying the antibody of Weidle.et.al in a similar manner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Waghray whose telephone number is 571-270-3063. The examiner can normally be reached on Monday-Thursday, 7.30AM-5.00PM, Est. alt. Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906 can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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